JUN - 7 2000

K001454

510(k) Summary of Safety and Effectiveness

Prepared May 5, 2000

TRADE NAME	SilverSpeed™ Hydrophilic Guidewire (.014" outer diameter, 'support' guidewires - 145cm, 165cm, 175cm, 200cm lengths)		
GENERIC NAME	Hydrophilic Guidewire	**CLASSIFICATION**	Class II (21 CFR 870.1330)
SUBMITTED BY	Micro Therapeutics, Inc. (MTI) 2 Goodyear Irvine, CA 92618	**CONTACT**	Maribelle Aguinaldo Regulatory Affairs (949) 837-3700
PREDICATE DEVICE	Micro Therapeutics, Inc. SilverSpeed™ Hydrophilic Guidewire, 510(k) K993297 (.014" outer diameter; lengths of 145cm, 165cm, 175cm, or 200cm)		
DEVICE DESCRIPTION	The SilverSpeed™ Hydrophilic Guidewire is a stainless steel guidewire with a radiopaque, platinum distal coil. The guidewire is hydrophilically coated from the shapeable platinum coil up to the proximal 30cm of the guidewire. Included within the sterile pouch is a torque device to assist in guidewire manipulation and a guidewire introducer to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.		
INDICATIONS FOR USE	The SilverSpeed™ Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.		
SAFETY AND PERFORMANCE TESTS	Biocompatibility of the SilverSpeed™ guidewire has been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the SilverSpeed™ guidewire when tested as an external communicating, blood contact, short duration (<24 hrs.) device. *In vitro* performance testing for changes implemented in the .014" support guidewires included dimensional inspection, tip flexibility, tip buckling, push force, and tip shape retention testing. All tests yielded acceptable results substantially equivalent to the predicate device.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The SilverSpeed™ Hydrophilic Guidewire is substantially equivalent to the predicate device in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Ms. Maribelle Aguinaldo
Manager, Regulatory Affairs
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K001454
SilverSpeed™ Hydrophilic Guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: May 8, 2000
Received: May 9, 2000

Dear Ms. Aguinaldo:

We have reviewed your Section 510(k) notifications of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notifications. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K001454

Device Name: SilverSpeed™ Hydrophilic Guidewire

Indications for Use: The Micro Therapeutics, Inc. SilverSpeed Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

(Division Sign-Off) 6/7/0
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001454

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** ______
(Per 21 CFR 801.109)